

Complete Summary

GUIDELINE TITLE

Febuxostat for the management of hyperuricaemia in people with gout.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Febuxostat for the management of hyperuricaemia in people with gout. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Dec. 29 p. (Technology appraisal guidance; no. 164).

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Chronic hyperuricaemia in conditions where urate/uric acid deposition has already occurred (including a history or the presence of tophi and/or gouty arthritis)

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
 Treatment

CLINICAL SPECIALTY

Family Practice
Geriatrics
Internal Medicine
Rheumatology

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To evaluate the clinical effectiveness and cost-effectiveness of febuxostat for the management of hyperuricemia in people with gout

TARGET POPULATION

People in England, Wales, and Northern Ireland with chronic hyperuricaemia in gout who are intolerant of allopurinol or for whom allopurinol is contraindicated

INTERVENTIONS AND PRACTICES CONSIDERED

Febuxostat within its marketing authorisation

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
 - Changes in serum uric acid levels
 - Frequency of gout flares
 - Reduction in tophi size
 - Side effects of treatment
 - Tolerance to treatment
 - Health-related quality of life
- Cost effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent

academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by the School of Health and Related Research (SchARR), University of Sheffield (see the "Availability of Companion Documents" field.)

Clinical Effectiveness

Critique of Manufacturer's Approach

Description of Manufacturer's Search Strategy and Comment on Whether the Search Strategy Was Appropriate

The searches undertaken by the manufacturer to identify all relevant randomised controlled trials (RCTs) were conducted in December 2007. The search strategy utilises terms to identify the condition (gout), the intervention (febuxostat) and the type of evidence (RCTs, economic analyses). No language restrictions appear to have been applied. The strategy is simple but effective and the methodological filters used to identify types of evidence are representative of some of the best ones available. Only three databases were searched however (PubMed, Embase and The Cochrane Library) so key data may have been missed, particularly regarding unpublished data (no research registers, such as the National Research Register or Current Controlled Trials, were searched). Other key databases overlooked include the Science Citation Index (Web of Science) and BIOSIS.

It is noted that the term allopurinol was omitted from the search strategy. Whilst this can be defended on the basis that the manufacturers were aware of head-to-head trials between febuxostat and allopurinol that are likely to be the most appropriate comparison, reference to previous allopurinol trials could provide reassurance that the head-to-head trials did not, by chance, favour or disfavour allopurinol. The clinical advisors have commented that the results for allopurinol appear to be lower than would have been expected from previous clinical trials.

Statement of the Inclusion/Exclusion Criteria Used in the Study Selection and Comment on Whether They Were Appropriate

Inclusion Criteria

Randomised phase II and phase III studies including the clinical effect of febuxostat on gout, compared to placebo or an active control.

Exclusion Criteria

- Non-randomised clinical studies, e.g., phase I studies on healthy volunteers
- Preclinical studies

Although the inclusion/exclusion criteria appear to be (mostly) appropriate there appears to be some irregularities in the manufacturer's submission (MS).

The statement of the decision problem proposes that the standard comparators to consider include alternative standard care (including sulphinpyrazone,

benzbromarone, probenecid, or a combination of those) for adults unresponsive or intolerant to allopurinol. Although inclusion of studies that assess the clinical effect of febuxostat on gout compared to active controls are most appropriate, the MS has also considered no treatment (i.e., placebo) as an option for standard care. The ERG acknowledges that no treatment (i.e., placebo) may be a viable option for some adults, particularly for patients unresponsive or intolerant to allopurinol, and is an appropriate comparator.

The manufacturer's inclusion/exclusion criteria for the clinical evidence does not specify restrictions by length of follow up; however, the pooled analyses (not meta-analysis) conducted by the manufacture excluded a four week, phase II, randomised placebo controlled trial. In addition, the cost-effectiveness section only included studies of at least 12 weeks duration to assess the clinical effect of febuxostat on gout. The MS does not provide a reason for the different inclusion/exclusion criteria between the two sections nor does it provide an appropriate rationale for limiting studies by duration.

Refer to Section 4.2 of the ERG report for more information on inclusion/exclusion criteria (see the "Availability of Companion Documents" field.)

NUMBER OF SOURCE DOCUMENTS

Clinical Effectiveness

Three randomized controlled studies and two open label extension studies were identified by the manufacturer.

Cost-Effectiveness

Three above-mentioned studies and a manufacturer's model were submitted.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology

considered in this appraisal and prepare an Evidence Review Group (ERG) report. The ERG report for this technology appraisal was prepared by the School of Health and Related Research (ScHARR), University of Sheffield (see the "Availability of Companion Documents" field.)

Clinical Effectiveness

Description and Critique of Manufacturer's Approach to Validity Assessment

The validity assessment tool used in the manufacturer's submission (MS) is not referenced, but the questions are adequate. The completed validity assessment tool for the three pivotal trials is reproduced in Table 5 of the ERG report (see the "Availability of Companion Documents" field). The ERG acknowledges the validity assessment tool used in the MS was appropriate; however, some further discussion around specific points is required.

Although the MS states that all studies (FACT, APEX and TMX-00-004) were double blind, it is unclear from the evidence provided in the MS whether investigators who administered the intervention were blinded to the treatment or if outcome assessors were blinded to the treatment allocation. In addition, the MS does not report if any of these studies assessed the success of blinding.

The MS states that the mean compliance rate (determined by pill count) ranged from 95.0% to 97.8% across the treatment groups in the FACT and APEX trials (data not reported for TMX-00-004 study). In general, the validity of a study may be threatened if attrition is more than 20%. In the FACT and APEX trials, 33% and 28% of patients prematurely discontinued treatment, respectively. However, all withdrawals were accounted for and an intention to treat (ITT) analysis was undertaken.

Ideally in an ITT analysis participants should be analysed in the groups to which they were randomised regardless of which (or how much) treatment they actually received, and regardless of other protocol irregularities, such as ineligibility. The MS states that all primary and secondary efficacy analyses for the FACT and APEX trials (no information provided on the TMX-00-004 trial) were performed on the ITT population, except for the secondary efficacy analyses for the percent reduction in primary tophus size and the reduction in the total number of tophi. The ITT population was defined as all randomised subjects who received at least one dose of study drug and who had serum uric acid (sUA) levels ≥ 480 micromol/L (8.0 mg/dL) or greater at day -2 as determined by the central laboratory. Although the post-randomisation inclusions were pre-specified, the ERG acknowledges that the removal of ineligible patients (with sUA levels < 480 micromol/L at day -2) from both study arms who received treatment after randomisation may be acceptable and will lead to an unbiased assessment of treatment effect in patients who do meet the inclusion criteria.

Describe and Critique the Statistical Approach Used

The manufacturer did not undertake a meta-analysis. The MS states that no meta-analysis was considered necessary as patient level data from pooled head-to-head randomised controlled studies (RCTs) was available which provided high

level evidence of efficacy and safety. Despite the notable differences (such as length of study, definition of renal function, intervention sites [country], inclusion of a placebo and febuxostat 240 mg/d group, and the use of lower doses of allopurinol based on renal function) between the studies, the rationale for presenting and pooling individual patient data from the FACT and APEX trials (provided as additional information when requested) was primarily based on the similarity of the design and patient selection criteria of the two head-to-head trials; however, the limitations and validity of this methodology was not discussed.

Critique of Submitted Evidence Syntheses

Meta-Analysis

The MS relies on a pooled analysis of data from the FACT and APEX trials and treats them as one large study. However, the ERG considers this type of data pooling to be inappropriate as it fails to preserve randomisation and introduces bias and confounding. A more satisfactory statistical technique involves combining the results from two or more separate studies in a meta-analysis. However, as requested, the results of such meta-analyses in the form of relative and absolute risk reductions using both the fixed and random effects models were not provided by the manufacturer. These meta-analyses have therefore been calculated (from data provided from the individual studies in the MS or data from the primary published peer reviewed clinical paper of the FACT study minus pooled results in the MS for data on the APEX trial), using the Cochrane Collaboration Review Manager 4.2.10 software.

Continuous and dichotomous data were combined using the inverse variance method of meta-analysis to give a weighted average of the effect estimates from the individual studies. Effect estimates for continuous data were obtained by comparing least squares mean (\pm standard deviation, SD) percentage change in outcome measure for each treatment group, from baseline to study end and are presented as a weighted mean difference (WMD) between treatments. The treatment goal outcomes were assessed as relative risk (probability) of reaching goal in one treatment group relative to other, during the trial period. It should be noted that a higher relative risk (or probability) of the outcome is desirable in the case of reaching treatment goal. Heterogeneity between trial results was explored using the χ^2 test and the I^2 measure.

A summary of the results from the meta-analysis are presented in Table 12 and Table 13 of the ERG report (see the "Availability of Companion Documents" field.)

Refer to Sections 4.2 and 4.3 of the ERG report (see the "Availability of Companion Documents" field) for more information on methods used to analyze the evidence.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals,

patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The manufacturer's submission presented an analysis of the cost effectiveness of febuxostat in comparison with fixed-dose allopurinol. A decision-tree model was provided to estimate the cost and health outcomes for patients with gout after initiation of urate-lowering therapy with febuxostat 80 mg or 120 mg daily, or allopurinol 300 mg daily.

The base-case economic analysis using pooled clinical data over a 1-year time horizon comparing febuxostat (80 mg/day and 120 mg/day) with fixed-dose allopurinol produced an incremental cost-effectiveness ratio (ICER) of 16,574 pounds sterling per quality adjusted life years (QALY) gained. An alternative base-case analysis based on a 2-year time horizon produced an ICER of 15,565 pounds sterling per QALY gained. The manufacturer presented the results of a probabilistic sensitivity analysis that gave a mean ICER of 16,324 pounds sterling per QALY gained (95% confidence interval [CI] 6281 pounds sterling to 239,928 pounds sterling per QALY). The cost-effectiveness acceptability curve reported that the probability that febuxostat 80 mg/day (titrated to 120 mg/day where appropriate) had an ICER lower than 20,000 pounds sterling per QALY gained compared with fixed-dose allopurinol was 63%.

The Evidence Review Group (ERG) noted a number of areas of uncertainty around the cost-effectiveness analyses undertaken in the manufacturer's submission.

The Committee discussed the exploratory analysis by the ERG of the incremental QALY gain associated with the effect of lowering the serum uric acid concentration. The overall incremental QALY gain (0.032) included both the incremental QALY gain from the avoidance of gout flares and the 'chronic utility gain' from the prevention of gout-related symptoms. This is much higher than the overall incremental QALY gain (0.006) obtained from including the avoidance of gout flares alone. The impact of this difference on the final ICER was proportionately substantial. The Committee noted that removing the component of incremental QALY gain associated with the 'chronic utility gain' from lowering serum uric acid concentration increased the base-case ICER from 15,000 pounds sterling to 81,000 pounds sterling per QALY gained over a 2-year time horizon. It considered, however, that uncertainty about the strength and nature of the relationship between serum uric acid concentration, gout flares and utility gain added to the uncertainties surrounding the manufacturer's base case. Although the Committee was persuaded that removal of the 'chronic utility gain' would lead to an underestimation of the long-term clinical benefits of febuxostat treatment, it considered that the true base-case ICER, even when compared with fixed-dose allopurinol, would be within a wide range of between 15,000 pounds sterling and 81,000 pounds sterling per QALY gained.

Overall, the Committee concluded that although febuxostat had been shown to be more effective than fixed-dose allopurinol in lowering serum uric acid concentration, it had not been shown to be clinically or cost effective compared with the more appropriate comparator of allopurinol up-titrated in accordance with established best clinical practice. However, it concluded that febuxostat should be recommended as an option for the management of chronic hyperuricaemia in gout for people who are intolerant of allopurinol, or for whom allopurinol is contraindicated.

Refer to Sections 3 and 4 of the original guideline document for details of the economic analyses provided by the manufacturer, the ERG comments, and the Appraisal Committee considerations.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Febuxostat, within its marketing authorisation, is recommended as an option for the management of chronic hyperuricaemia in gout only for people who are intolerant of allopurinol (as defined below) or for whom allopurinol is contraindicated.

For the purposes of this guidance, intolerance of allopurinol is defined as adverse effects that are sufficiently severe to warrant its discontinuation, or to prevent full dose escalation for optimal effectiveness as appropriate within its marketing authorisation.

People currently receiving febuxostat should have the option to continue therapy until they and their clinicians consider it appropriate to stop.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of febuxostat for the management of hyperuricemia in people with gout

POTENTIAL HARMS

The most common side effects associated with febuxostat are diarrhoea, nausea, headache, liver function test abnormalities and rash. Uncommon side effects include fatigue, oedema, dizziness, altered sense of taste, increase in blood amylase, decrease in platelet count, increase in blood creatinine, and arthralgia. Rare side effects include nervousness, insomnia, asthenia and renal insufficiency. The Summary of Product Characteristics (SPC) states that treatment with febuxostat is not recommended for people with ischaemic heart disease or congestive heart failure.

For full details of side effects and contraindications, see the summary of product characteristics (SPC).

CONTRAINDICATIONS

CONTRAINDICATIONS

For full details of contraindications, see the summary of product characteristics (SPC).

QUALIFYING STATEMENTS

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- This guidance represents the view of the Institute, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.
- Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their

responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

- The Healthcare Commission assesses the performance of National Health Service (NHS) organizations in meeting core and developmental standards set by the Department of Health in "Standards for better health" issued in July 2004. The Secretary of State has directed that the NHS provides funding and resources for medicines and treatments that have been recommended by the National Institute for Health and Clinical Excellence (NICE) technology appraisals normally within 3 months from the date that NICE publishes the guidance. Core standard C5 states that healthcare organisations should ensure they conform to NICE technology appraisals.
- "Healthcare Standards for Wales" was issued by the Welsh Assembly Government in May 2005 and provides a framework both for self-assessment by healthcare organisations and for external review and investigation by Healthcare Inspectorate Wales. Standard 12a requires healthcare organisations to ensure that patients and service users are provided with effective treatment and care that conforms to NICE technology appraisal guidance. The Assembly Minister for Health and Social Services issued a Direction in October 2003 which requires Local Health Boards and NHS Trusts to make funding available to enable the implementation of NICE technology appraisal guidance, normally within 3 months.
- NICE has developed tools to help organisations implement this guidance (listed below). These are available on the NICE website (<http://guidance.nice.org.uk/TA164>) [see also the "Availability of Companion Documents" field]).
 - Costing report and costing template to estimate the savings and costs associated with implementation
 - Audit support for monitoring local practice

IMPLEMENTATION TOOLS

Audit Criteria/Indicators

Patient Resources

Quick Reference Guides/Physician Guides

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Health and Clinical Excellence (NICE). Febuxostat for the management of hyperuricaemia in people with gout. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Dec. 29 p. (Technology appraisal guidance; no. 164).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 Dec

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: Professor Keith Abrams, Professor of Medical Statistics, University of Leicester; Dr Ray Armstrong, Consultant Rheumatologist, Southampton General Hospital; Dr Jeff Aronson, Reader in Clinical Pharmacology, University Department of Primary Health Care, University of Oxford; Dr Darren Ashcroft, Reader in Medicines Usage and Safety, School of Pharmacy and Pharmaceutical Sciences, University of Manchester; Professor David Barnett (*Chair*) Professor of Clinical Pharmacology, University of Leicester; Dr Peter Barry, Consultant in Paediatric Intensive Care, Leicester Royal Infirmary; Professor Stirling Bryan, Head, Department of Health Economics, University of Birmingham; Professor John Cairns, Public Health and Policy, London School of Hygiene and

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Febuxostat for the management of hyperuricaemia in people with gout. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Dec. 2 p. (Technology appraisal 164). Available in Portable Document Format (PDF) from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).

- Febuxostat for the management of hyperuricaemia in people with gout. Costing template and report. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Dec. Various p. (Technology appraisal 164). Available in Portable Document Format (PDF) from the [NICE Web site](#).
- Febuxostat for the management of hyperuricaemia in people with gout. Audit support. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008. 4 p. (Technology appraisal 164). Available in Portable Document Format (PDF) from the [NICE Web site](#).
- Febuxostat for the management of hyperuricaemia in people with gout. Evidence review group report. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Mar 31. 73 p. (Technology appraisal 164). Available in Portable Document Format (PDF) from the [NICE Web site](#).

Print copies: Available from the National Health Service. (NHS) Response Line 0870 1555 455. ref: N1755. 11 Strand, London, WC2N 5HR.

PATIENT RESOURCES

The following is available:

- Febuxostat for hyperuricaemia in people with gout. Understanding NICE guidance - Information for people who use NHS services. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Dec. 4 p. (Technology appraisal 164).

Electronic copies: Available in Portable Document Format (PDF) from the [National Institute for Health and Clinical Excellence \(NICE\) Web site](#).

Print copies: Available from the NHS Response Line 0870 1555 455. ref: N1756. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

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